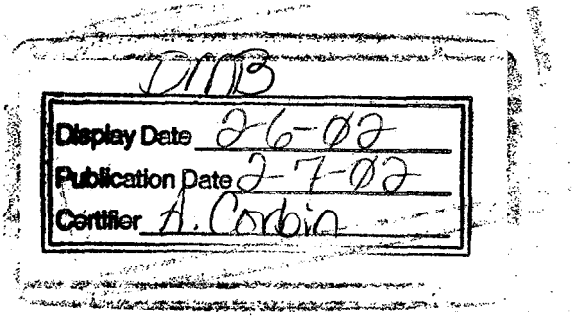


**DEPARTMENT OF HEALTH AND HUMAN 'SERVICES**

**Food and Drug Administration**

**21 CFR Part 522**

## Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Intervet, Inc. The supplemental NADA provides for an additional dose of trenbolone acetate and estradiol implant for use in feedlot heifers for increased rate of weight gain and improved feed efficiency.

**DATES:** This rule is effective *[insert date of publication in the* **Federal Register].**

**FOR FURTHER INFORMATION CONTACT:** Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish PI., Rockville, MD 20855, 301-827-0223, e-mail: dbenz@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed supplemental NADA 140-992 that provides for REVALOR-200 ear implants containing 200 milligrams (mg) trenbolone acetate and 20 mg estradiol for heifers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. The supplemental NADA is approved as of December 6, 2001, and the regulations are amended in 21 CFR 522.2477 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food

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and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing,animals qualifies for 3 years of marketing exclusivity beginning December 6, 2001, because the application contains substantial evidence of the effectiveness of the drugs involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the application- and conducted or sponsored by the applicant.

FDA has determined under 21 CFR 25,33(a)(l) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

**List of Subjects in 21 CFR Part 522**

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

## PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority: 21 U.S.C. 360b.**

2. Section 522.2477 is amended by adding paragraph (d)(2)(i)(C) to read as follows:

**§ 522.2477 Trenbolone acetate and estradiol.**

* * * * *

(d) * * *

(2) * * *

(i) * * *

(C) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(A) of this section.

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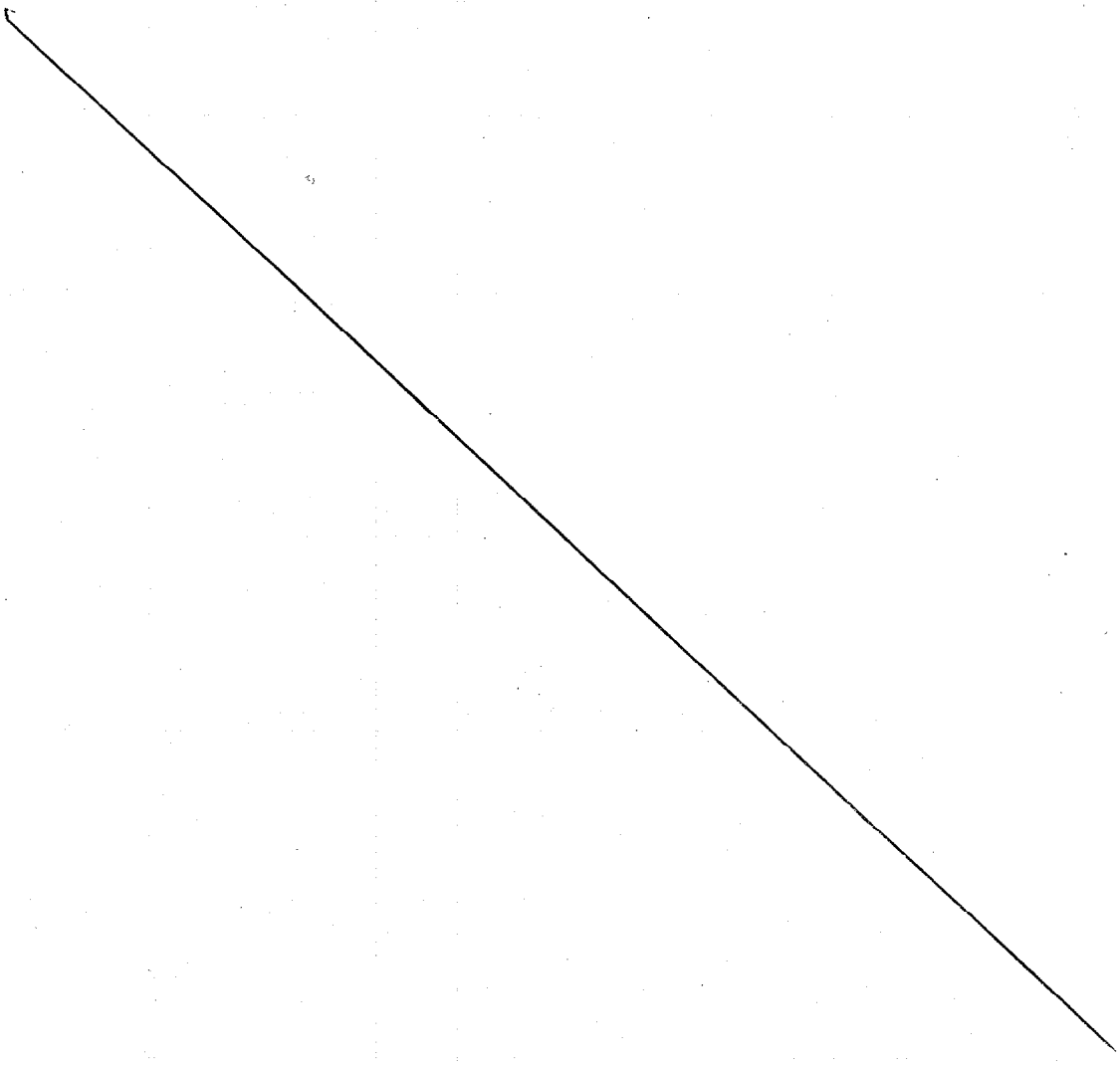

Dated: 1/11/02

January 11, 2002.

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Claire M. Lathers,
Director,
Office of New Animal Drug Evaluation
Center for Veterinary Medicine.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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